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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,579	03/12/2004	Kazuko Shinozaki	081356-0210	6471

22428 7590 03/27/2007
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EXAMINER	
KUMAR, VINOD	
ART UNIT	PAPER NUMBER
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,579	SHINOZAKI ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/09/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-5 and species rd29A gene promoter and the DREB1A gene in the paper filed on November 6, 2006 is acknowledged.

Applicants argue that amended claims 6-10 underscore the fact that the claimed product is produced by the method of claims 1-5. Applicants further argue that based on this relationship between the two claim groupings, Group II should be rejoined with elected Group I (response, page 6, lines 1-3).

Applicant's arguments were fully considered and were found persuasive. Accordingly, restriction requirement between product and process claims is WITHDRAWN. Claims 6-10 are rejoined with claims 1-5. Claims 1-10 in conjunction elected species rd29A gene promoter and the DREB1A gene encoding the DNA binding protein are examined on merits in the instant Office action. This restriction is made FINAL.

Applicants are advised that if any claims including all the limitations of an allowable claim examined here are presented in a continuation or divisional application; such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449 filed on May 9, 2004 is attached to the instant Office action.

Priority

3. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Application No. 2003-71082, filed on March 14, 2003 has been received. However, English translation of the priority document has not been received. Also claim to foreign priority must be checked on Oath or declaration.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The specification to which the oath

or declaration is directed has not been adequately identified. Oath or declaration fails to identify Application number. See MPEP § 602.

Specification

The disclosure is objected to because of the following informalities:

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. For example, sequence identifiers are missing on page 23, lines 15-16; page 25, line 19.

Description of drawings do not have SEQ ID listed with the sequences.. For example, the sequences in Figures 2-9 must be referred to by their sequence identifiers as required by 37 CFR 1.821.

If the sequences appearing in the specification do not have sequence ID numbers assigned to them, then an amendment to the sequence listing will be required as well. There must not be any new matter submitted, therefore it is important to be careful to include only the sequences that are already disclosed in the current specification. Failure to correct the deficiency will be held a non-responsive to this Office action.

6. All the labels in Figure 1 must be identified in brief description to the drawings.

7. Labels "strain 9", "strain 10" and "strain 11" in Figures 10-11 must be identified as transgenic lines in brief description to the drawings.

Appropriate corrections are required.

Claim Objections

8. Claims 2-5 and 7-10 are objected to because of the following informalities:

In claims 2-5 and 7-10, non-elected subject matter must be removed from the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "improved", which is confusing since the recitation "improved" is a relative term lacking comparative basis. The metes and bounds of the recitation are not defined. Dependent claims 2-5 and 7-10 fail to overcome this deficiency.

Claims 1, 3-4, 6, and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "gene" which is confusing since the limitation "gene" implies that the structure comprises the coding sequence and the associated promoter,

terminator and enhancer encoding regions are also a part of the structure (see The Federal Register, Vol. 66, No. 4, Friday, January 5, 2001 at page 1108, left column, Endnote 13). In the instant case, Applicants do not appear to describe such gene associated nucleic acid sequences. It is suggested that "gene" be amended to "coding sequence".

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "using a gene wherein a DNA encoding a protein", which is confusing, since it is unclear whether "gene" in the recitation encodes "protein" of the recitation. It is unclear which "DNA" is being referred to? Is it the "gene" that comprises a DNA sequence which encodes a protein or what? It is unclear what is intended? Dependent claims 2-5 and 7-10 fail to overcome this deficiency.

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "regulates the transcription of a gene located downstream of the element is ligated downstream of the stress-responsive promoter", which is confusing, since it is unclear what is intended. Is it transcription of an another gene located downstream of a gene comprising a stress responsive promoter that is being regulated or what? It is unclear what the recitation "ligated downstream of the responsive promoter is being referred to. Dependent claims 2-5 and 7-10 fail to overcome this deficiency.

Claims 1, 3-4, 6 and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "downstream", which is confusing since the metes and bounds of the recitation are unclear and not defined.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because preamble is inconsistent with the last recited method step. Claim 1 is missing the essential step of expressing a gene. The preamble recites a method of improved rooting efficiency and/or prolonged vase life, whereas last recited method step is transforming a plant with a gene. But according to preamble last method step has to be expression of said gene in the plant. See MPEP § 2172.01.

Claims 4-5 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "stringent conditions", which is confusing since it is unclear what level of stringency is encompassed by "stringent conditions". Page 32 of specification gave examples but did not define "stringent conditions".

Claims 4-5 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "complementary" which is confusing since the recitation reads on a 2 mer sequence or a different sequence. It is suggested that "complementary" be amended to "fully complementary".

Claims 4-5 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "nucleotide sequence", since it is unclear which sequence is being referred to because elected species DREB1A or rd29A are not identified by their SEQ ID Numbers. DREB1A or rd29A isolated from different sources do not contain identical nucleotide sequences. It is unclear how one skilled in the art would make homology comparisons if the reference sequences, such as, DREB1A or rd29A are not defined. It is unclear what is intended?

Appropriate action/corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plant with improved rooting efficiency and/or prolonged vase life and a method of producing said transgenic plant comprising transformation of a plant with a gene comprising the stress-responsive gene promoter rd29A operably linked to a DNA sequence of DREB1A (SEQ ID NO: 1) encoding the DREB1A protein (SEQ ID NO: 2), does not reasonably provide enablement for (a) a nucleotide sequence which has less than 100% sequence identity to the nucleotide sequence of rd29A gene promoter, (b) a DNA sequence which has less than 100% sequence identity to the nucleotide sequence of DREB1A (SEQ ID NO: 1) encoding DREB1A protein (SEQ ID NO: 2), (c) a DNA hybridizing to the nucleotide sequence of rd29A under stringent conditions, and d) a DNA hybridizing to the DNA sequence of DREB1A (SEQ ID NO: 1) under stringent conditions. The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art which it pertains, or which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue

experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Claims are broadly drawn to a transformed plant and a method of producing said transformed plant having improved rooting efficiency and/or prolonged vas life, comprising transformation of a plant with a gene comprising a stress-responsive promoter sequence and a DNA sequence encoding a protein that binds to a stress responsive promoter and regulates the expression of a gene which comprise a stress responsive element in its promoter.

The specification teaches a transgenic plant of *Chrysanthemum* and a method of producing said transgenic plant comprising transformation of said plant with rd29A-DREB1A expression vector, wherein rd29A is a stress-responsive promoter operably linked to a DNA sequence encoding the DNA binding protein DREB1A as defined in SEQ ID NO: 2. The transgenic plants exhibited increased salt tolerance and, improved rooting efficiency and prolonged vase life. See pages 41-46, Examples 1-4, Tables 1-4.

Claims 4 and 9 are directed to a nucleotide sequences having at least 80% sequence identity to a DNA sequence of DREB1A gene (SEQ ID NO: 1). The claims encompass deletion, substitution, addition of one or several nucleotides within SEQ ID NO: 1 which encodes a DNA binding transcription factor DREB1A (SEQ ID NO: 2). The specification provides guidance on using SEQ ID NO: 1 (DREB1A gene) encoding SEQ

ID NO: 2 in a method of producing transgenic plants with improved rooting efficiency and/or prolonged vase life. However, specification does not provide guidance on a method of using DREB1A gene, comprising deletion, additions, substitutions of one or more nucleotides.

Keskin et al. (Protein Science, 13:1043-1055, 2004) teach that proteins with similar structure may have different functions. Besides, Thornton et al. (Nature structural Biology, structural genomics supplement, November 2000) teach that structural data may carry information about the biochemical function of the protein. Its biological role in the cell or organism is much more complex and actual experimentation is needed to elucidate actual biological function under *in vivo* conditions. Furthermore, Guo et al. (PNAS, 101: 9205-9210, 2004) teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as 80% sequence identity to a DNA sequence of DREB1A gene (SEQ ID NO: 1) would encompasses more than a single amino acid changes in the encoded protein, except changes due to codon degeneracy. Neither the state of art nor Applicants provide guidance as to how inoperable embodiments can be readily eliminated other than random trial and error. A DNA sequence with 80% identity to SEQ ID NO: 1 (DREB1A gene) would encompass changes in the functionally important domain(s) of the encoded protein. In the absence of guidance, it would have been highly unpredictable at the time the claimed invention was made that a DNA sequence which has at least 80% sequence identity to a DNA sequence of DREB1A gene (SEQ ID NO: 1) would encode

a functionally active protein that retains the ability to bind a stress responsive element of a stress responsive gene and thereby regulate the expression of said stress responsive gene. In the absence of adequate guidance, undue experimentation would have been required by a skilled artisan at the time claimed invention was made to determine how to use a DNA sequence which has at least 80% sequence identity to the DNA sequence of DREB1A gene (SEQ ID NO: 1), in a method of producing a transgenic plant with improved rooting efficiency and/or prolonged vas life. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claims 5 and 10 are directed to a nucleotide sequences having at least 80% sequence identity to a DNA sequence of a rd29A gene promoter. The claims encompass deletion, substitution, addition of one or several nucleotides within the DNA sequence of rd29A gene promoter. The specification provides guidance on using rd29A promoter in a method of producing transgenic plants with improved rooting efficiency and/or prolonged vase life. However, specification does not provide guidance on a method of using rd29A promoter comprising deletion, additions, substitutions of one or more nucleotides. It is well established in the art that changing a single base randomly would abrogate promoter activity. For example, see Kim et al. (Plant Molecular Biology, 24:105-117, 1994) who teach that small alterations in a nos (nopaline synthase) promoter strongly influenced promoter strength. In the absence of adequate guidance, it would have been highly unpredictable at the time claimed invention was made to

predict with reasonable expectation of success that DNA sequences having less than 100% sequence identity to the wild-type rd29A promoter sequence would (a) exhibit promoter activity in a stress responsive manner and (b) used in the instantly claimed method of producing a transgenic plant having improved rooting efficiency and/or prolonged vase life. Undue experimentation would have been required by a skilled artisan at the time the claimed invention was made to determine how to use said sequences which have less than 100% sequence identity with rd29A promoter in a method of improving rooting efficiency and/or prolonged vase life.

Furthermore, claims 4 and 9 are directed to any DNA comprising a nucleotide sequence that can hybridize to a DNA complementary to DREB1A gene (SEQ ID NO: 1) because the stringent conditions recited in the claim would encompass hybridization of a DNA that is unrelated to DREB1A gene (SEQ ID NO: 1). This implies that sequences, which do not encode a protein, or encode a protein, which is unrelated to DREB1A, would also hybridize to DREB1A gene (SEQ ID NO: 1) under said conditions of hybridization. In the absence of adequate guidance, undue experimentation would have been required by one skilled in the art to determine how to use said unrelated sequences in a method of producing a transgenic plant with increased rooting efficiency and/or prolonged vase life.

Furthermore, claims 5 and 10 are directed to any DNA comprising a nucleotide sequence that can hybridize to a DNA complementary to rd29A promoter sequence because the stringent conditions recited in the claim would encompass hybridization of a DNA sequence that is unrelated to rd29A promoter sequence, implying that a

nucleotide sequence lacking promoter activity would also hybridize to rd29A promoter sequence. In the absence of adequate guidance, undue experimentation would have been required by one skilled in the art to determine how to use said unrelated sequences in a method of producing a transgenic plant with increased rooting efficiency and/or prolonged vase life.

Claim 1 and 6 are directed to any gene which comprises a promoter with a stress-responsive element and a coding sequence that encodes a protein that binds to a stress-responsive element of any stress-responsive promoter of any gene. While the specification provides guidance on using rd29A promoter operably linked to DREB1A coding sequence to produce a transgenic plant with improved rooting efficiency and/or prolonged vas life, it does not enable all nucleotide sequences encoding other genes with a stress responsive promoter and a coding sequence operably linked thereto. Undue experimentation would have been required by one skilled in art at the time the claimed invention was made to isolate other genes from other sources. See In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one

skilled in the art to make and use the claimed invention. Therefore, it is maintained that the claimed invention is not enabled as commensurate in scope with the claims.

11. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are broadly drawn to a transformed plant having improved rooting efficiency and/or prolonged vas life comprising transformation of a plant with a gene comprising a stress-responsive promoter sequence and a DNA sequence encoding a protein that binds to a stress responsive promoter and regulates the expression of a gene which comprise a stress responsive element in its promoter.

The specification describes a transgenic plant of *Chrysanthemum* and a method of producing said transgenic plant comprising transformation of said plant with rd29A-DREB1A expression vector, wherein rd29A is a stress-responsive promoter operably linked to a DNA sequence encoding a DNA binding protein DREB1A as defined in SEQ ID NO: 2. The transgenic plants exhibited increased salt tolerance and, improved rooting efficiency and prolonged vase life. See pages 41-46, Examples 1-4, Tables 1-4.

Claims 4 and 9 are directed to nucleotide sequences having at least 80% sequence identity to a DNA sequence of DREB1A gene (SEQ ID NO: 1). The claims encompass deletion, substitution, addition of one or several nucleotides within SEQ ID

NO: 1 which encodes a DNA binding transcription factor DREB1A (SEQ ID NO: 2). Claims 5 and 10 are directed to nucleotide sequences having at least 80% sequence identity to a DNA sequence of a rd29A gene promoter. The claims encompass deletion, substitution, addition of one or several nucleotides within the DNA sequence of rd29A gene promoter. Claim 1 and 6 are directed to any gene which comprises a promoter with a stress-responsive element and a coding sequence that encodes a protein that binds to a stress-responsive element of any stress-responsive promoter of any gene. Furthermore, claims 4 and 9 are directed to any DNA comprising a nucleotide sequence that can hybridize to a DNA complementary to DREB1A gene (SEQ ID NO: 1) because the stringent conditions recited in the claim would encompass hybridization of a DNA that is unrelated to DREB1A gene (SEQ ID NO: 1). Further, claims 5 and 10 are directed to any DNA comprising a nucleotide sequence that can hybridize to a DNA complementary to rd29A promoter sequence because the stringent conditions recited in the claim would encompass hybridization of a DNA that is unrelated to rd29A Claims 5 and 10 are directed to nucleotide sequences having at least 80% sequence identity to a DNA sequence of a rd29A gene promoter.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The

court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

The specification does not have adequate written description for genus of genes encoding protein(s) that bind to a stress-responsive element, genus of sequences which

have less than 100% sequence identity to DREB1A gene (SEQ ID NO: 1), genus of sequences that have less than 100% sequence identity to rd29A promoter sequence, genus of sequences that hybridize to DREB1A gene (SEQ ID NO: 1) and genus of sequences that hybridize to rd9A promoter sequence under current written description guidelines. Specification does not describe these undisclosed structures of Applicant's broadly claimed genus and one skilled in the art cannot reliably predict the structure of these sequences based upon the disclosure of rd29A and DREB1A.

Furthermore, said structures of Applicant's broadly claimed genus are not correlated to the function of improved rooting efficiency and/or prolonged vas life in a transgenic plant. Further, Applicants have failed to describe conserved functional domains that are shared by these undisclosed structures of their broadly claimed genus. Applicants have failed to reduce their broadly claimed genus to practice.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasuga et al. (Nature Biotechnology, vol. 17, pp. 287-291, March 1999).

Kasuga et al. disclose a transgenic plant and a method of making said transgenic plant comprising transformation of said plant with an expression vector comprising stress-inducible rd29A promoter operably linked to drive expression of a nucleotide sequence (100% sequence identity to instant DREB1A gene) encoding stress-inducible and the DNA binding protein of DREB1A, wherein DREB1A binds to a stress-responsive element of a stress-inducible promoter in response to environmental stresses like, freezing, drought or salt. The reference further discloses a recombinant vector, stress (drought, salt or freezing) tolerant transgenic plant and a method of producing said transgenic plant comprising said stress-inducible promoter operably linked with a stress inducible coding region of *Arabidopsis* CBF3 (a DREB transcription factor). The transgenic plants exhibited increased tolerance to salt and drought (dehydration) stresses. See in particular, page 287, abstract; page 288, Figures 1 and 2; page 289, Figures 3-5; page 290, Table 1; 1st and 2nd columns of page 290; page 291, experimental protocol.

The property of regulating the transcription of a gene comprising a stress-responsive element is inherent to the method using DREB1A gene disclosed in the reference.

The property of hybridization to the complementary DNA sequence is inherent to the method using DREB1A coding sequence or rd29A promoter disclosed in the reference.

The property of improved rooting efficiency and/or prolonged vase life is inherent to the method of producing a transformed plant comprising DREB1A operably linked to rd29A promoter disclosed in the reference.

See MPEP 2111.02. Also see *In re Cruciferous Sprout Litig.*, 301 F.3d 1343,1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) where a claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase "rich in glucosinolates" helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently "rich in glucosinolates"). Furthermore, see *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

Accordingly, Kasuga et al. anticipate the claimed invention.

Conclusions

13. Claims 1-10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER